

#### **IV. REMARKS/ARGUMENTS**

The Specification has been amended to update the priority data of the present application.

##### **A. Status of Claims**

Claims 38 and 39 have been amended. Claims 40-45 have been cancelled without prejudice. New claims 48-50 have been added.

Support for new claim 48 is found, e.g., at page 12, lines 19-20 and support for new claims 49-50 is found, e.g., at page 11, lines 4-6. It is respectfully submitted that no new matter has been added to the application by virtue of the present amendment.

##### **B. Rejection under 35 U.S.C. 103 (a) over Baker et al., Engelhardt et al., Engelhardt, and Distel et al.**

In the Office Action, the Examiner rejected claims 38-44 and 46-47 under 35 U.S.C 103 (a) over US 4,569,937 (hereinafter "Baker et al."), Engelhardt et al. Inflamm. Res. 44:423-433 (1995) (hereinafter "Engelhardt et al."), Engelhart Brit J. Rheumatol. 1996:35 (suppl.1):4-12 (hereinafter "Engelhardt"), and Distel et al. Brit. J. Rheumatol. 1996:35(suppl.1):68-77 (hereinafter "Distel et al."). The Examiner stated that "it would have been prima facie obvious to one of ordinary skill in the art ... to modify the Baker reference analgesic composition by substituting the NSAID meloxicam (for the NSAID ibuprofen) or supplementing Baker's composition with meloxicam in light of the benefits of meloxicam ... as taught by the Englehardt et al., Engelhardt and Distel et al. references."

Initially, it is noted to the Examiner that the claims recite, in part, "an analgesic combination consisting essentially of meloxicam ... and oxycodone" (emphasis added). Therefore, the claims do not encompass an analgesic combination of three analgesics (e.g., meloxicam, oxycodone and ibuprofen). Accordingly, the Examiner's rejection with respect to

“supplementing” Baker’s composition (i.e., a narcotic analgesic and ibuprofen) with meloxicam is not applicable to the pending claims.

Regarding the remainder of the rejection, it is initially noted that the purported invention of Baker et al. is directed to pharmaceutical compositions of narcotic analgesics and ibuprofen which “... exhibit unexpectedly enhanced analgesic activity ...” (See Abstract). Baker et al. is limited to combinations wherein the NSAID is ibuprofen and does not teach or suggest that the purported “unexpectedly enhanced analgesic activity” would occur with an NSAID which is different than ibuprofen.

Therefore, modifying the formulation of Baker et al. in view of Engelhardt et al., Engelhardt, and Distel et al., as proposed by the Examiner, by substituting ibuprofen with meloxicam would result in a dosage form which is not directed to the principle of operation described in Baker et al. (i.e., the purported synergism of narcotic analgesics and ibuprofen). The Examiner is reminded that “[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” See MPEP 8<sup>th</sup> edition, Revision 2, p.2100-132.

Therefore, it is respectfully requested that the 35 U.S.C. 103(a) rejection over Baker et al., Engelhardt et al., Engelhardt, and Distel et al. be removed.

**C. Rejection under 35 U.S.C. 103 (a) over Baker et al., Engelhardt et al., Engelhardt, and Distel et al. in view of Mayer et al.**

In the Office Action, the Examiner further rejected claims 38-44 and 46-47 under 35 U.S.C. 103 (a) over Baker et al., Engelhardt et al., Engelhardt, and Distel et al. in view of US 5,834,479 (hereinafter “Mayer et al.”). The Examiner stated that the Mayer et al. is cited “[t]o the extent that the Baker, Engelhardt et al., Engelhardt and Distel et al. references fail to teach

the administration of the analgesia active agent ... 'before, ... with, or after' administration of the oxycodone."

This rejection is respectfully traversed. In view of the arguments presented above, it is respectfully submitted that the combination of Mayer et al., Engelhardt et al., Engelhardt and Distel et al. does not teach or suggest the present invention which is directed, in part, to "an analgesic combination consisting essentially of meloxicam ... and oxycodone ..." As Mayer et al. is relied upon by the Examiner solely for describing the administration of one agent "before, ... with, or after" the other agent, it is respectfully submitted that Mayer et al. does not cure the deficiencies of Baker et al., Engelhardt et al., Engelhardt and Distel et al. as discussed above.

Therefore, it is respectfully requested that 35 U.S.C. 103(a) rejection over Baker et al., Engelhardt et al., Engelhardt and Distel et al. in view of Mayer et al. be removed.

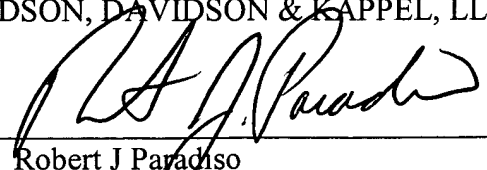
V. CONCLUSION

The present application is respectfully submitted as being in condition for allowance, and applicants respectfully request such action.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: \_\_\_\_\_

  
Robert J Paradiso  
Reg. No. 41,240

DAVIDSON, DAVIDSON & KAPPEL, LLC  
Patents, Trademarks and Copyrights  
485 Seventh Avenue, 14<sup>th</sup> Floor  
New York, New York 10018  
(212) 736-1940